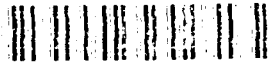


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**TESTING AND EVALUATION OF THE
BEAR MEDICAL SYSTEMS, INC.
BEAR 33 VOLUME VENTILATOR SYSTEM**

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December 1990

Final Report for Period January 1989 - June 1989

Approved for public release; distribution is unlimited.

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**USAF SCHOOL OF AEROSPACE MEDICINE
Human Systems Division (AFSC)
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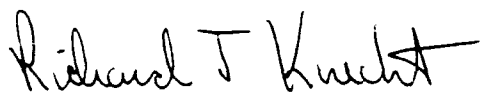
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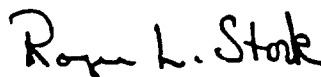
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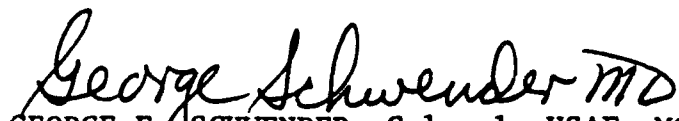
This report has been reviewed and is approved for publication.



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TABLE OF CONTENTS

	<u>Page</u>
BACKGROUND	1
DESCRIPTION	1
Bear 33 Volume Ventilator.....	1
LS 420 Humidifier.....	3
Litter Sled	4
METHODS	5
Test Setup	5
Performance Checks	6
Baseline Performance Assessment	6
Electromagnetic Interference	7
Vibration	8
Environmental	8
Altitude	9
Rapid Decompression.....	9
Airborne Feasibility	10
Followup Testing	10
RESULTS	11
Baseline Performance Assessment	11
Electromagnetic Interference	11
Vibration	11
Environmental	12
Altitude	12
Rapid Decompression.....	14
Airborne Feasibility	14
Followup Testing	15
CONSIDERATIONS	15
Procedural Recommendations	15
Suggested Modifications	16
CONCLUSIONS	17
ACKNOWLEDGMENTS	17
REFERENCES.....	18
APPENDIX A: Specifications and Operating Features of the Bear 33 Volume Ventilator.....	19
APPENDIX B: Specifications and Operating Features of the LS 420 Humidifier.....	21

List of Figures

Fig.
No.

1. The Bear 33 Volume Ventilator with patient breathing circuit, mounted on litter sled.....	2
2. The Bear Model LS 420 Humidifier.....	3
3. The litter sled.....	4
4. The Bear 33 Ventilator System secured with J-bolts to the NATO litter.....	5
5. Bear oxygen percentage preset at ground level v. percentage actually delivered at 10,000 ft.	13
6. Bear oxygen percentage delivery at altitude when preset at 40% at ground level	13

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TESTING AND EVALUATION OF THE BEAR MEDICAL SYSTEMS, INC. BEAR 33 VOLUME VENTILATOR SYSTEM

BACKGROUND

Military Airlift Command (MAC) is tasked with the aeromedical evacuation (AE) mission for the Department of Defense (DOD). As technological advances continue to prolong life for critically ill patients, there is a growing need for a means to safely and effectively transport ventilator-dependent patients. The Puritan Bennett Corporation MA-1 ventilator was used on most AE missions. However, the MA-1 is a relatively heavy, bulky ventilator which was designed for use in fixed medical facilities. Additionally, the MA-1 failed to meet electromagnetic interference standards and its use requires a waiver from the MAC surgeon.

A new class of ventilators has been designed for hospital use outside of intensive care units, or treatment of patients who are somewhat less stable than the usual home care patients. These ventilators are less sophisticated than critical care ventilators, yet have more features than traditional home care models. The new ventilators offer nonphysiologic breathing patterns previously available only on critical care models, while retaining the portability, cost, simplicity of operation and safety features necessary for use in patient transport. The Bear Medical Systems, Inc. Bear 33 Volume Ventilator, designed for use in the hospital, home, or ambulance/mobile environment, addresses and solves many of the problems encountered while transporting a ventilator-dependent patient. The purpose of our evaluation was to determine the ability of the Bear 33 Volume Ventilator and its components to safely and effectively meet the needs of the ventilator-dependent patient in the demanding aeromedical environment.

DESCRIPTION

Three basic components were evaluated.

Bear 33 Volume Ventilator

The Bear 33 (Fig. 1) is a volume ventilator which utilizes a motor-driven piston to drive air into the patient breathing circuit (Bear Medical Systems, Inc. Model 51000-08020). Unlike critical care ventilators, the Bear 33 was not designed to use separate sources of compressed gas. A passive one-way valve within the ventilator allows the patient to breathe spontaneously. A fully-charged internal battery allows temporary backup for up to 1 h in the event of power loss, but should not be used for extended transportation operation. A large-capacity external battery is available to supply power during extended portable operation when alternating current (AC) power is not available; however, the battery was not submitted for testing. Dedicated meters for both external and internal batteries on the front panel provide easy visibility of charge status.

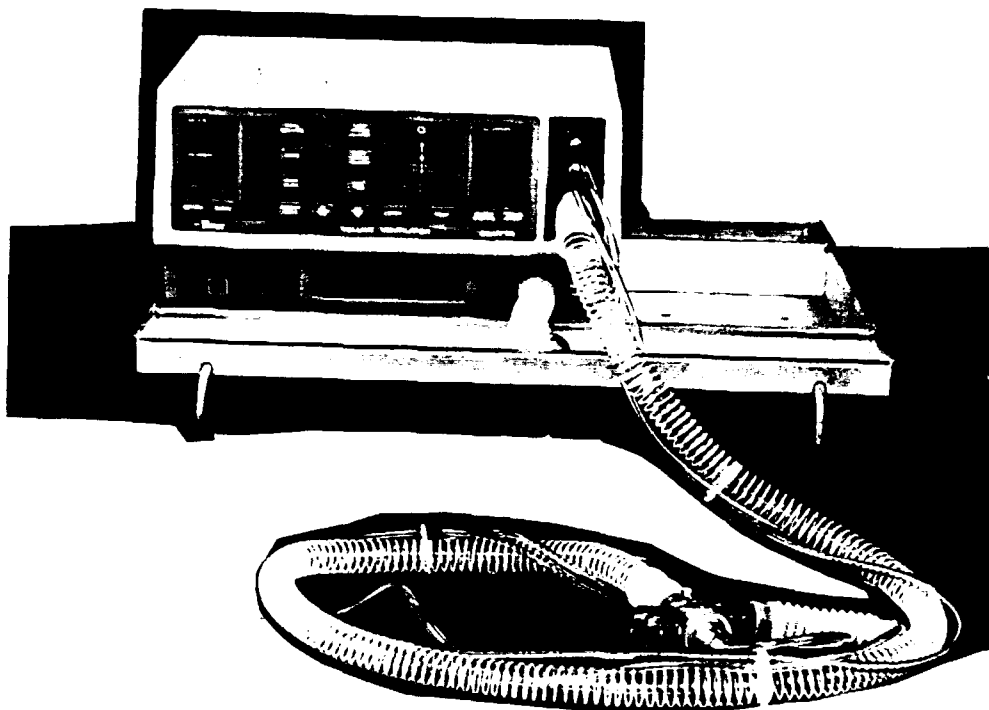


Figure 1. The Bear 33 volume ventilator with patient breathing circuit, mounted on litter sled.

The ventilator is equipped with visible and audible low- and high-pressure alarms with adjustable limits. Breathing-circuit pressures are measured at the patient connection; this allows for more reliable measurement of patient airway pressures than does measuring within the ventilator at the inspiratory port. A high-pressure alarm warns of pressure increases caused by decreases in patient compliance, increases in airway resistance, or breathing-circuit occlusion. The low-pressure alarm warns of disconnection or leaks in the breathing circuit.

The exhalation valve is located close to the patient connection and simplifies the breathing circuit by eliminating the need for an exhalation hose. A separate positive end expiratory pressure (PEEP) valve can be attached to the exhalation manifold if required. The ventilator is PEEP compatible for 0 - 20 cmH₂O.

Oxygen (O₂) enrichment is accomplished by mixing O₂ with air in an accumulator before it is drawn into the piston. With this passive system, the volume fraction of inspired oxygen (FIO₂) supplied to the patient depends on the O₂ flow and the minute volume. A graph is used to estimate the O₂ flow which must be set for the desired FIO₂. Since the Bear 33 is not equipped with an integral O₂ monitor, the FIO₂ must be monitored with an external O₂ monitor.

The Bear 33 ventilator provides 3 modes of ventilation: control, assist-control, and synchronous intermittent mandatory ventilation (SIMV). Tidal volume, rate, peak flow, and assist sensitivity are the 4 primary controls for setting the ventilation parameters. The Bear 33 also provides a tamper resistant panel lock that automatically relocks in 15 s and a test button that allows a quick check of the displays and the integrity of the liquid crystal displays (LCDs). The operating features and specifications of the ventilator are listed in Appendix A.

LS 420 Humidifier

The Bear 33 Ventilator System provides humidification of inspired air through the Bear Medical Systems, Inc. Model LS 420 Humidifier (Fig. 2). The LS 420 is a general purpose humidifier designed for most respiratory therapy uses. Humidification of air delivered to patients is especially important in the aeromedical environment where ambient humidity is quite low. The humidifier provides temperature control, various levels of humidity, visual indication of normal operation, visual alert of low water level, visual indicator of warm-up period, and visual alert of inoperative condition. The LS 420 performance characteristics and specifications are listed in Appendix B.

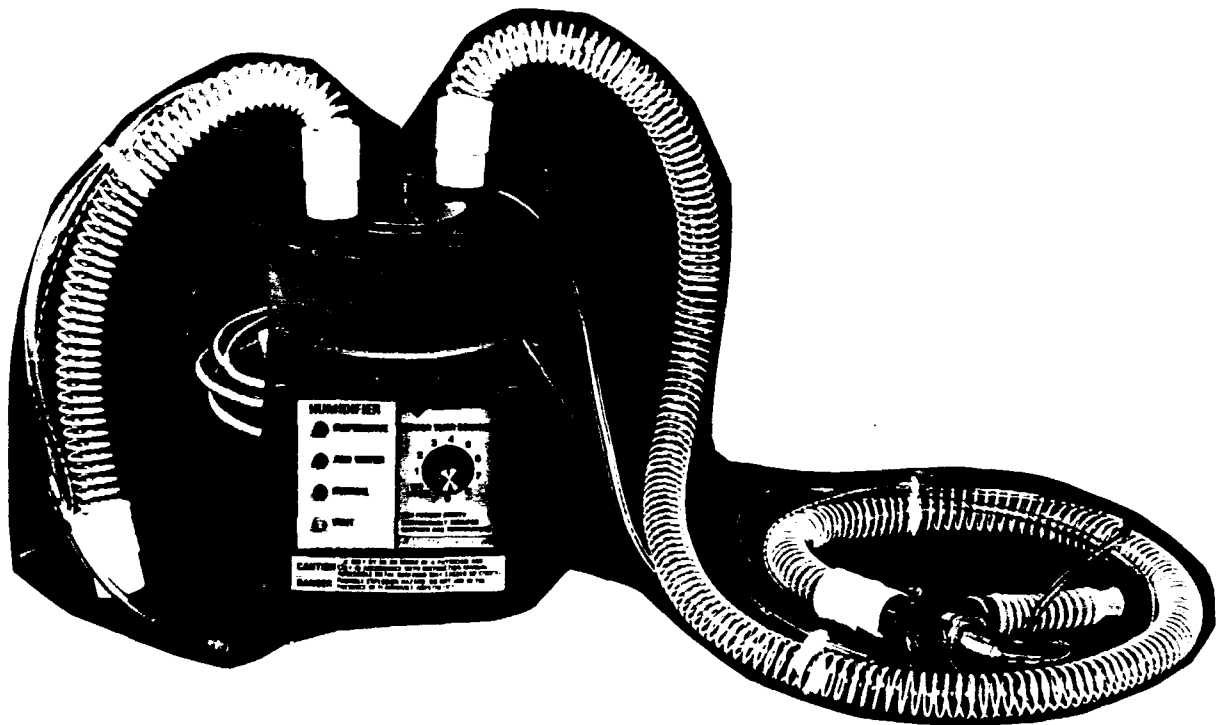


Figure 2. The Bear Model LS 420 humidifier.

The humidifier is composed of a cover and jar assembly which plugs directly into the control module and latches mechanically. The heater assembly forms a

portion of the jar bottom and is in direct contact with the water. The heater assembly contains a silicon "blanket" heater, a thermistor sensor, and a thermostat which prevents heater runaway if all other controls fail. Within the cover and jar assembly, air is directed down the inlet tube and past a one-way check leaf. The air then bubbles up through the temperature-controlled water and over the water surface to the outlet port of the cover assembly.

Litter Sled

The Bear 33 Ventilator System includes an aluminum litter sled on which both the ventilator and humidifier can be bolted and secured (Fig. 3). The litter sled dimensions are: height, 5 cm (2 in.); width, 76.2 cm (30 in.); depth, 45.7 cm (18 in.); and weight 2.27 kg (5 lb). This mounting device uses three J-bolts to safely secure the ventilator and humidifier to a standard North Atlantic Treaty Organization (NATO) litter which is placed in the securing stanchions of the aircraft. Figure 4 illustrates how the components are mounted on the litter sled which is in turn secured on a NATO litter.

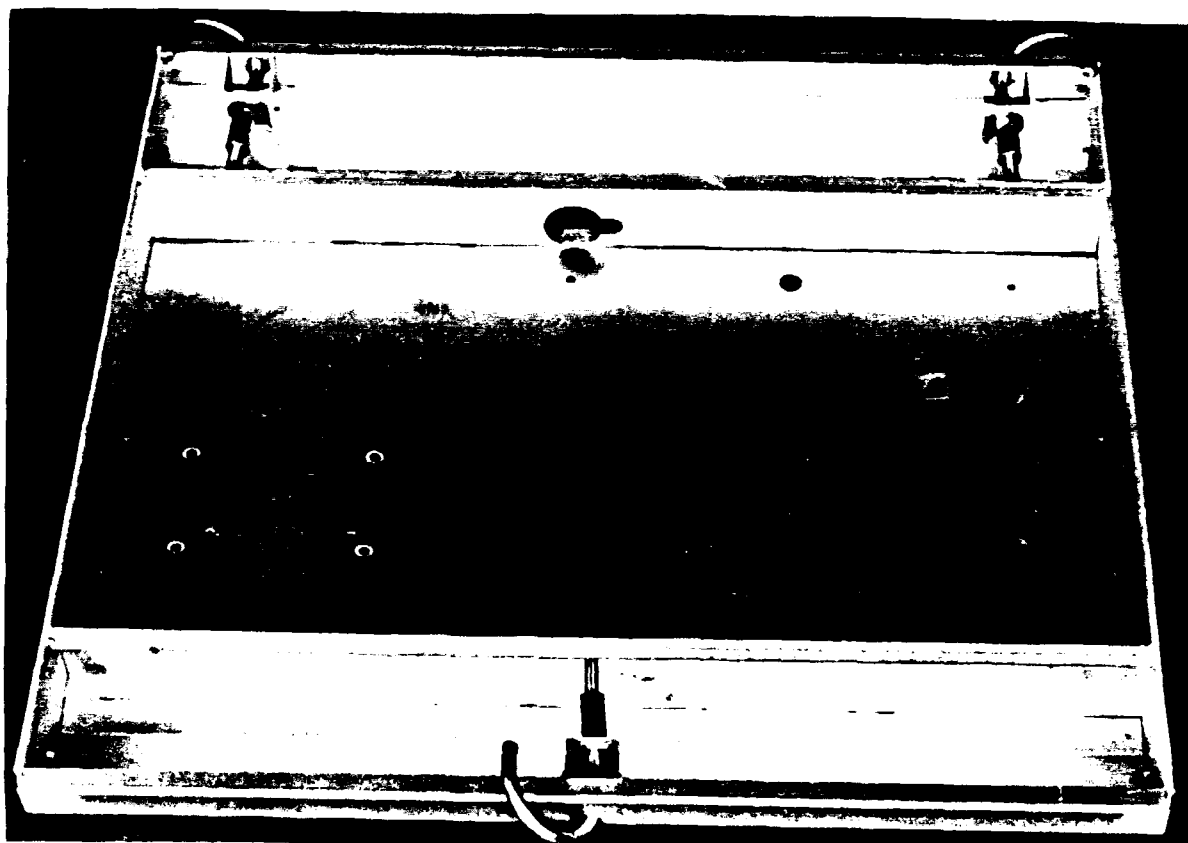


Figure 3. The litter sled.

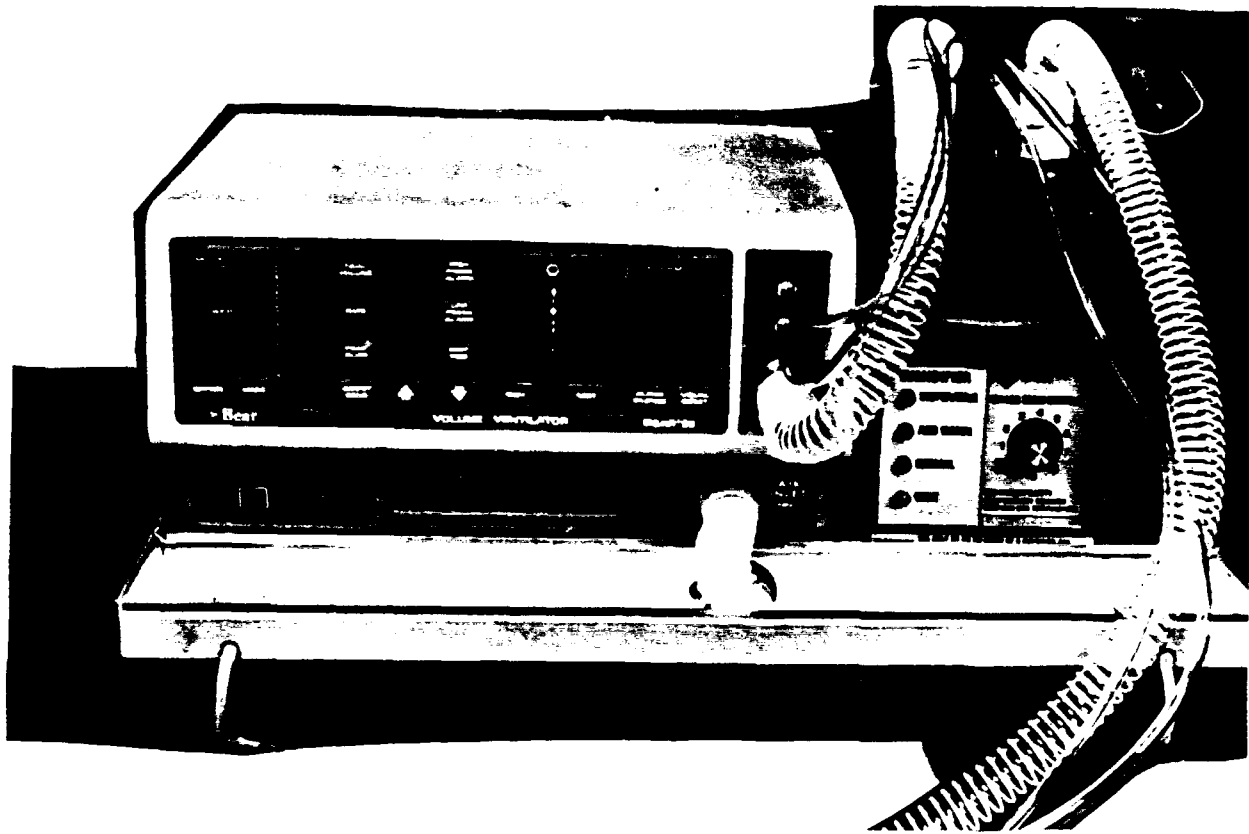


Figure 4. The Bear 33 ventilator system secured with J-bolts to the NATO litter.

METHODS

Test methods and performance criteria used were derived from various military standards (1-4), nationally recognized performance guidelines (5), and Bear 33 Clinical Instruction Manual (6). The Aeromedical Research Function developed testing procedures that covered safety and human factor issues regarding the ventilator system. A test setup and a performance check were developed that verified proper functioning of the equipment under various conditions.

Test Setup

Using the patient breathing circuit provided by the manufacturer (used throughout our evaluation), the ventilator and humidifier were connected to a Bio-tek Instruments Model VT-1 Ventilator Tester. A Grant Instruments Model 1201 Squirrel Meter/Logger with a Vaisala Model HMP 31 UTA Humidity and Temperature Probe were placed inline to monitor the humidity and temperature of the air being delivered by the ventilator system. A Catalyst Research MiniOX III Oxygen Monitor was used to monitor the percentage of oxygen being delivered by the ventilator. When concentrations of oxygen higher than 21% were used for testing, the additional oxygen

was delivered to the ventilator's accumulator using standard medical grade therapeutic oxygen tubing connected to a 15 lpm oxygen flowmeter.

Performance Checks

Data was collected by computer whenever possible. This process simplified the plotting and analysis of the data. If the data was of such a nature that the computer could not collect it, the data was manually recorded on a Data Collection Sheet. Information specifically relating to the test setup was logged on a Test Information Sheet.

Generally, the ventilator was set to deliver approximately 12 breaths per minute (bpm) with a tidal volume of 0.7 l. Unless otherwise noted, the ventilator was tested in the control mode with the high alarm set at 70 cmH₂O and the Low Alarm set at 10 cm H₂O.

The VT-1 measured and recorded 17 parameters in the "Full Test" mode, and 4 parameters in the "Status Test" mode. The Full Test mode included the following: breath rate, inspiratory to expiratory ratio (I:E ratio), tidal volume, minute volume, inspiratory time, inspiratory hold time, expiratory time, expiratory hold time, cycle time, peak airway pressure, peak lung pressure, end expiratory pressure, mean airway pressure, inspiratory flow, expiratory flow, airway pressure (AP) variation, and volume variation. Status test mode included breath rate, tidal volume, minute volume and I:E ratio.

The compliance of the VT-1 was set at .05 l/cmH₂O, and airway resistance set at 20 cmH₂O/l/min, because these settings most closely simulate the lung characteristics of an adult ventilatory patient.

Three Full Tests at ambient conditions (22.0±2 °C, 750±10 mmHg barometric pressure, 50±30% relative humidity) were run at 5 min intervals, before and after each major test (i.e., vibration testing). The Status Test data was continuously monitored, but not recorded. During each major test, every 15 min the Full Test was run and all the parameters were recorded. Values derived from the 3 pretest recordings were used as baseline references in determining variation percentages recorded during testing. Post-performance check values were used to identify any deviation from the pre-performance check which might indicate damage to the ventilator due to the testing. Recordings were graphed and analyzed using Cricket Graph software.

Baseline Performance Assessment

The purpose of the Baseline Performance Assessment (BPA) was to quantitatively measure and record the respirator's performance under standard ambient conditions prior to adverse testing. The BPA is used as a reference for subsequent performance testing to verify the manufacturer's compliance with contract specifications; and to ensure safe operation prior to testing. Specifically, the BPA included the following:

Initial Inspection. The initial inspection was an operational verification which compared the respirator's operating characteristics (i.e., ventilation rate, delivered volumes, inspiratory/expiratory ratio) to its numerically displayed parameters. These operating characteristics were measured, recorded and compared to the manufacturer's published specifications.

Electrical Safety. The electrical safety test consists of ground resistance and leakage current measurements and a visual examination of the ventilator and the humidifier. Ground resistance was measured between the ground pin of the power cord and the chassis of the ventilator. The leakage current was measured with the power on and off, with controls adjusted to yield the highest leakage current (unit off), with the power supply ground intact (normal polarity), with the ground lifted (normal polarity), and ground lifted (reverse polarity). All measurements were made using a Dempsey Model 431 Safety Analyzer.

Battery Operation/Charging Characteristics. These tests were performed to verify the ventilator's battery operation time and charging characteristics as described in the Clinical Instruction Manual. These tests were performed on the ventilator only because the humidifier does not have a battery power source. The ventilator's battery was discharged and then charged for 8 h on 110 VAC/60 Hz. The ventilator was set for a tidal volume of 650 ml, 12 BPM, and a peak flow of 37 liters per minute to simulate typical operational settings. It was connected to the test lung and operated until the "Lo Batt" alarm sounded. The alarm was silenced and the ventilator continued to operate until the "Vent Inop" alarm activated and the ventilator quit functioning. This charge and operation cycle was repeated with the ventilator operating at its peak performance (highest settings possible).

Electromagnetic Interference

The purpose of these tests was to verify compliance with MIL-STD-461C. Specific tests were as follows:

Radiated Emissions (RE-02). RE-02 measures radiated emissions generated by the ventilator and/or the humidifier. Excessive emissions could interfere with aircraft navigation and communication equipment. The ventilator was tested operating on 110 VAC/60 Hz, on internal battery, and while charging on 110 VAC/60 Hz. The humidifier was tested while operating on 110 VAC/60 Hz, its only power source. During the tests, the high pressure alarm was activated to provide the most electromagnetic interference possible.

Conducted Emissions (CE-03). CE-03 measures emissions generated by the ventilator and/or the humidifier and conducted back up the power line. Excessive conducted emissions could affect the aircraft power supply and/or other systems powered from it. The ventilator was tested while operating and charging on 110 VAC/60 Hz. The humidifier was tested while operating on the same power supply.

Radiated Susceptibility (RS-02). RS-02 determines whether the ambient electromagnetic fields encountered in flight interfere with ventilator and/or humidifier operation. The ventilator and humidifier were exposed to the electromagnetic induction fields described in the Aeromedical Research Function Procedures Guide (7). During exposure, the ventilator was operated on both 110 VAC/60 Hz and battery power; and the humidifier was operated on 110 VAC/60 Hz. Ventilator and humidifier functions and alarms were carefully monitored during these tests.

Conducted Susceptibility (CS-06). CS-06 determines if the ventilator and humidifier will operate safely on the aircraft's noisy, fluctuating power supply. Electrical voltages and waveforms specified in MIL-STD-461C were conducted from the power source of 110 VAC/60 Hz to both the ventilator and the humidifier. During this test, functions and alarms were carefully monitored.

Vibration

These tests were designed to determine an item's durability and performance during worst case scenario vibrations. The ventilator was subjected to vibration tests in accordance with MIL-STD-810D. These tests consist of random (11 to 2,000 Hz) and sinusoidal (5 to 500 Hz) curves on x, y, and z axes. The vibration table was controlled by an Unholtz-Dicky control panel, operated by technicians from the USAFSAM Engineering and Maintenance Services Branch. During sinusoidal test, the ventilator was operated and vibrated for 5 sweeps of 15-min duration (for a total of 75 min) on each axis. During random tests, the ventilator was operated and vibrated for 30 min on each axis. Before and after each axis, a visual examination of the ventilator was performed, and VT-1 measurements were recorded.

Environmental

Environmental tests were tailored versions (based on the aeromedical operational environment) of those found in the MIL-STD-810D. These tests measured the system's performance under varying temperature and humidity conditions encountered during transport. Only the ventilator was inside the environmental chamber, the VT-1 test lung was outside the chamber. At the end of each test, the chamber was dehumidified and the temperature was changed to 23.9 °C (75 °F) to return to existing ambient conditions. The ventilator remained inside the chamber for 30 min during the post-test stabilization period, then post-test measurements were taken.

High Temperature: Operation: 49 °C±2 °C (120 °F±3.6 °F) for 2 h
Storage: 60 °C±2 °C (140 °F±3.6 °F) for 6 h

Low Temperature: Operation: 0 °C±4 °C (32 °F±7.2 °F) for 2 h
Storage: -40 °C±2 °C (-40 °F±3.6 °F) for 6 h

Humidity: Operation: 94±4% relative humidity, 29.5 °C±2 °C (85 °F±3 °F) for 4 h

Altitude

We tested the effects of reduced barometric pressure on the operation of the ventilator system through a series of 6 hypobaric chamber "flights." During the first 2 flights, the entire system (ventilator and humidifier) was tested for changes in operation affected by the varying ambient pressure. The standard flight protocol for the first 2 altitude tests was to climb to 10,000 ft (atmospheric pressure of 522 mmHg) at an ascent rate of 500 ft/min. The ascent was stopped at 2,000 ft increments to zero the VT-1 lung analyzer transducers and compensate for the change in atmospheric pressure. A full test (with all 17 parameters) was recorded and the high and low pressure alarms were checked at each 2,000 ft increment. At 10,000 ft, the chamber was stabilized and 3 full tests were recorded at 5-min intervals.

The next 4 altitude tests were performed to evaluate how increasing and decreasing ambient pressure would affect the percent oxygen being delivered to the patient. The tests were set up identical to the first 2 altitude tests except that we did not use the humidifier. Also, the ascent/descent rate was 5,000 ft per minute instead of 500 ft per minute. In addition to the VT-1 full test, 3 oxygen percentage readings were taken at each 2,000 ft increment, with oxygen percentage settings of 20, 40, 60, and 80% respectively. We determined the correct oxygen flow (in liters per minute) for the desired oxygen levels by using the oxygen accumulator chart provided in the Bear 33 Clinical Instruction Manual.

Rapid Decompression

Decompressions are uncommon; however, if one were to occur, the ventilator should not present a hazard to the patient, crew, or aircraft operations. Pre- and post-tests were done using the VT-1. For operation while inside the chamber, the ventilator and humidifier were attached to a Michigan Instruments Model 1600 mechanical lung analyzer, which simulated the patient's lungs. We used this simplified mechanical test lung because of the possibility of damage to the sensitive VT-1. Pressure transducers, to measure the chamber pressure and the peak airway pressure at the mechanical lung analyzer, were connected to a Gould Series 2000 strip-chart recorder, to log the performance of the ventilator during the decompression. With the ventilator system and test equipment placed inside the sealed chamber, the chamber was depressurized to 8,000 ft equivalent. Over a period of 60 s the chamber was depressurized to 40,000 ft equivalent. The ventilator system was observed and allowed to continue to operate for 5 min; then the chamber was returned to ground level. Posttests were done using the VT-1, followed by placing the ventilator system back in the chamber. The entire procedure was repeated twice, with the decompressions occurring over periods of 7 and 1 s.

Airborne Feasibility

The purpose of airborne testing is to evaluate the ventilator system's compatibility with each of MAC's aeromedical evacuation airframes. Potentially, this device could be used to ventilate patients on several of MAC's airframes, including C-9, C-12, C-21, C-130 and C-141 aircraft; and UH-1 and UH-60 helicopters. However, since both the humidifier and the ventilator require a 110 VAC/60 Hz power source, which is unavailable on the C-12, C-21 aircraft, and UH-1 and UH-60 helicopters, testing was conducted on the C-9A and C141B aircraft by two aeromedical research technicians who were qualified and current on the airframes used. (Note: While airborne testing on the C-130 was not done due to time limitations and aircraft availability, a form and fit evaluation was done on the C-130 mockup, located in Bldg 820 of Brooks AFB, Texas.) During the tests, the ventilator and humidifier were operating for the duration of the flights. Oxygen from the aircraft therapeutic oxygen system was attached to the ventilator and adjusted to deliver 60% oxygen. The ventilator was monitored by the Catalyst Research MiniOX III Oxygen Monitor, and connected to the Medical Development Ltd Model LS-122 Test Lung. Tidal volume, rate, I:E ratio, and oxygen percentage were recorded at 15-min intervals. Pre- and post-test measurements were also recorded. On the C-9, the system was powered by 115 VAC/60 Hz aircraft power. On the C-141, the same power was provided by a frequency converter. Although a power supply is not currently available on the C-12 and C-21 aircraft, form and fit evaluations were conducted to verify the feasibility of future use with an external battery power source. Additionally, a form and fit evaluation was done on the C-130 mockup located in Bldg. 820, Brooks AFB, TX.

Set-up and securing methods were evaluated, as well as integration with aircraft oxygen and electrical systems. The structural soundness of the ventilator was also evaluated during the enplaning, enroute, and deplaning stages of each aeromedical evacuation mission. Use and storage of the carrying case was evaluated. Crew acceptability was evaluated during interaction with the medical crew.

Followup Testing

During Operational Testing and Evaluation of the Bear 33 by the MAC Airlift Center, a change in the PEEP was observed by aeromedical evacuation crewmembers. MAC requested that we retest the Bear using the AMBU Model 20 PEEP Valve and the Instrumentation Industries Model BE 142 Magnetic PEEP Valve. A series of vibration and altitude tests were performed to determine why variations in the AMBU valve settings were observed; and to compare and contrast between the two valves.

MAC also submitted a disposable breathing circuit tubing (Baxter Airlife Cat. No. 003725) for evaluation. Their intention was to use the Baxter tubing in place of the nondisposable Bear patient breathing circuit.

RESULTS

Baseline Performance Assessment

Initial Inspection. The humidifier and the ventilator both meet operational performance standards.

Electrical Safety. Measured ground resistance was 76 milliohms for the humidifier and 68 milliohms for the ventilator. Maximum chassis leakage current was 10 μ for the humidifier and 12 μ for the ventilator. Those values are well within the USAF electrical safety requirements.

Battery Operation and Charging Characteristics. After a 12-h battery charge on 110 VAC/60 Hz, battery operation time was 2 h and 15 min before the low-battery alarm activated. The alarm was silenced and the ventilator continued to function for another 25 min. During the second test, the tidal volume, breath rate, and peak flow were set for maximum values. After the 12-h battery charge on 110 VAC/60 Hz the ventilator operated for a total of 1 h and 15 min with the low-battery alarm activating at the 1 h point. These battery operation/charge times were within the contract specifications (a minimum of 1 h operation after 24 h charge time).

Electromagnetic Interference

The ventilator and humidifier passed all electromagnetic interference tests.

Vibration

There were no problems with the operation of the ventilator; however, during x-axis sinusoidal testing, the humidifier lid popped off at 22 Hz on the first downsweep. We replaced the lid and resumed testing. The lid twisted off again at 27 Hz on the next upsweep, and again between 22 - 25 Hz on the next downsweep. At this point the ADD WATER indicator came on, even though the humidifier was still half full. Adding water solved the problem. We manually held the lid on for the next 3 x-axis tests. During y-axis sinusoidal on the first sweep, the lid twisted off between 22 and 30 Hz. During the third sweep, the humidifier INOP indicator came on at 15 Hz, quickly followed by the NORMAL indicator. The INOP indicator came back on and remained illuminated during sweeps 4 and 5. Throughout the vibration tests, the ventilator itself performed correctly and presented no problems.

After the vibration tests, a visual inspection of the humidifier revealed that a screw and metal clip from a terminal on the incoming power terminal block had become completely unscrewed and disconnected. No evidence of arcing was noted in the electrical compartment. During the post-test operational check, all the unit's indicator lights illuminated upon power up, as required. After a few seconds, the indicators went off, followed by illumination of the INOP indicator 1 to 2 s later. The INOP indicator remained on until the humidifier was powered down.

These occurrences indicated a failure of the heater assembly or heater control unit. A small amount of water was on the heater assembly pin after the last vibration test. The water or the loose screw may have caused a shorting of the heater control printed circuit board (PCB).

We recommended that all screws, nuts, and bolts should have lock washers; and that a better method of securing the humidifier be used to prevent air leaks and water spills. The manufacturer provided the lock washers, and changed the size of the lip seal gasket, to eliminate the possibility of the cover separating from the jar. The manufacturer's engineers concluded that the humidifier malfunctioned because of a faulty control PCB. They replaced the PCB, and sent us a humidifier with all modifications for repeat vibration testing. During the repeat vibration testing no further problems were noted with the humidifier.

During vibration testing the nuts which secured the sled to the litter required frequent checking and tightening. These nuts were impossible to tighten manually, without use of a wrench.

Environmental

The Bear 33 Ventilator system passed all environmental testing.

Altitude

At an equivalent altitude of 10,000 ft, both the ventilator and the humidifier operated satisfactorily. The ventilator maintained the ground level settings (within 5%). No malfunctions were observed during or after the tests.

During the tests with a supplemental oxygen source hooked up to the ventilator accumulator, the oxygen percentage delivered to the test lung changed with the varying altitude. As altitude increased, an increase in oxygen percentage occurred, and with decreased altitude a corresponding decrease in oxygen percentage. The highest percent change from ground level values was recorded at 10,000 ft, which is illustrated in Figure 5. For example, in the first test at 10,000 ft, with the oxygen flow set to deliver 80%, the oxygen monitor displayed 88% oxygen. Figure 6 shows the effect altitude had on the oxygen percentage reading when the oxygen flow had been set at 40% at ground level, reinforcing the premise that an oxygen monitor must be used during flight.

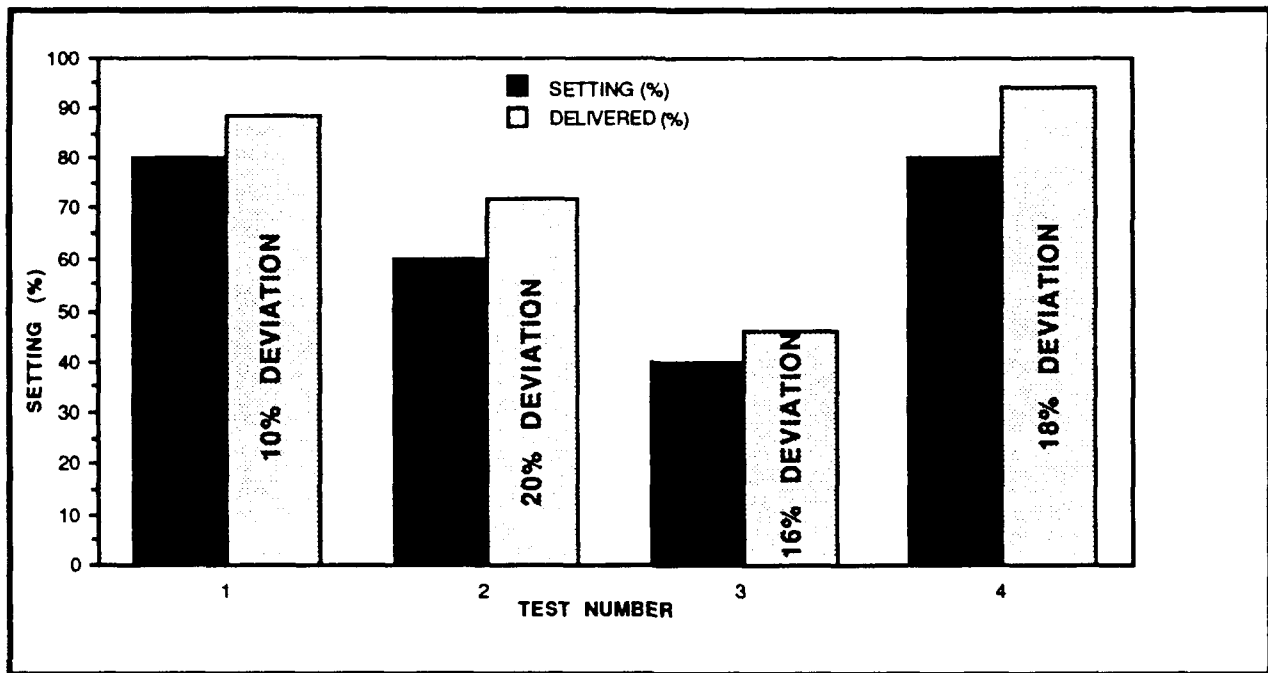


Figure 5. Bear oxygen percentage preset at ground level v. percentage actually delivered at 10,000 ft.

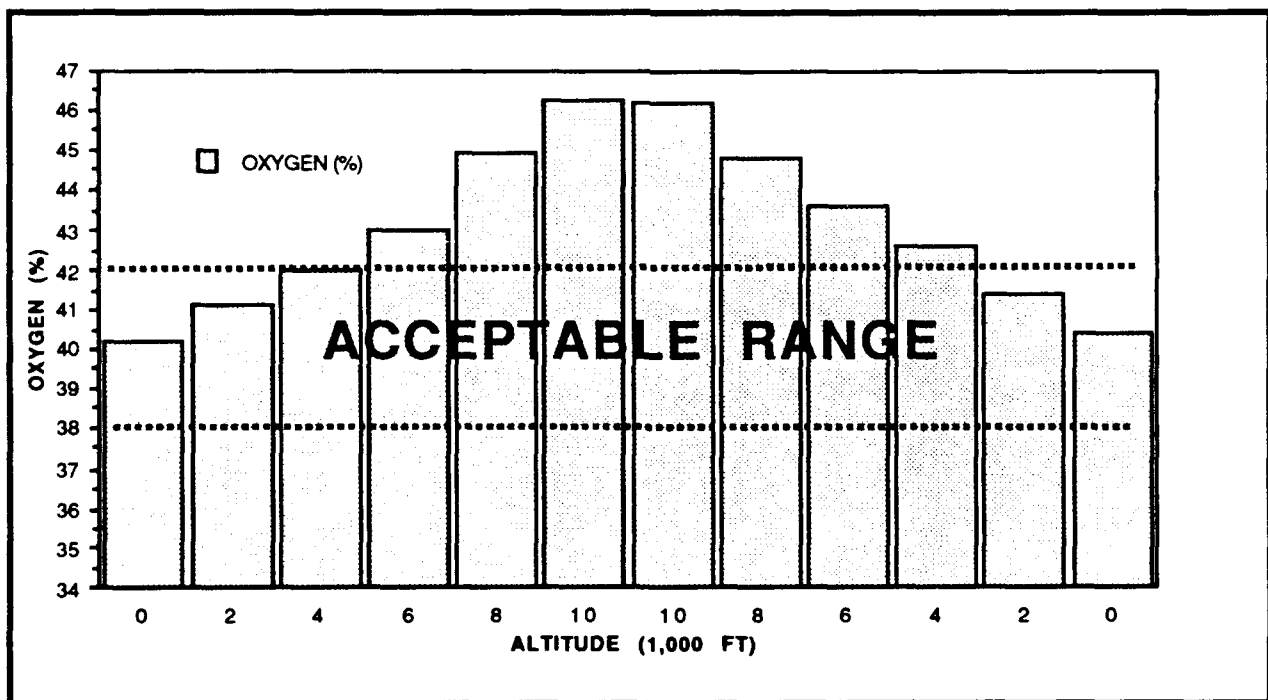


Figure 6. Bear oxygen percentage delivery at altitude when preset at 40% at ground level.

Rapid Decompression

During the 1-s decompression, the ventilator ceased functioning, and was inoperative for a total of 19 s before resuming operation. During the 7-s decompression, the ventilator was inoperative for 17 s. The ventilator continued operation during the 60-s decompression, but the respiratory cycle became progressively longer, from 6.6 s to 14.4 s at the end of the rapid decompression (RD). The peak airway pressure also increased, from a baseline of 15 cmH₂O to 33 cmH₂O at the end of the decompression. The maximum peak airway pressure recorded during all 3 decompressions was below 60 cmH₂O, the maximum allowed by the ventilator before the safety relief valve opens.

The results of these tests are typical of respirators under rapid decompression conditions. Rapid decompression effects on ventilator operations can be neutralized by prompt adjustment of the ventilator and oxygen source, once pressure inside the aircraft is stabilized.

Airborne Feasibility

This evaluation confirmed that the Bear 33 Ventilator system will successfully function on the C-9, C-130, and C-141. Ventilator operational characteristics and inline humidity readings of the patient breathing circuit demonstrated that the Bear 33 Ventilator system operates in the operational environment, according to contract and manufacturer specifications. The ventilator was easy to enplane, secure onboard, and deplane. Modifications to the J-bolts would allow the litter sled to be more easily and securely mounted on the litter. User feedback in regards to ease of operation was very favorable. The oxygen accumulator chart is only available in the Clinical Instruction Manual and the users would prefer a smaller chart attached to the ventilator.

While the C-9 has the required 115 VAC/60 Hz power available, for use on the C-130 and C-141, an approved power inverter or frequency converter must be used. Although the C-12 and C-21 do not currently have a 110 VAC/60 Hz power source available, the fit and form evaluation demonstrate that integrating the ventilator on these aircraft is feasible, if a small inverter or an external battery is provided as the primary power source.

The carrying case was very large and bulky, and required carrying by two people. The handles, which are in the middle of each side (1 handle per side), did not allow safe, stable carrying. The case tended to spontaneously rotate on the axis created at the center of the case where the handles were located, twisting the hands and wrists of the carriers.

The audible alarms were difficult to hear over the normal noise of the aircraft environment. The medical crew and/or attendants will have to monitor the system closely, and rely primarily on the visual alarms.

Followup Testing

Although both PEEP valves passed the vibration and altitude tests, the AMBU valve was more accurate. On the average, the AMBU valve maintained pressures within 2.8% of the set values, with the maximum deviation being 6.7% from the set value. On the average, the Instrumentation Industries valve maintained pressures within 3.5% of the set values, with the maximum deviation being 9.8% from the set value.

The AMBU valve control knob must be taped in place to prevent shifting during flight.

The Instrumentation Industries valve did not fit the breathing circuit and did not come with a connector. We used the connector provided with the AMBU valve to connect the Instrumentation Industries valve to the circuit. Also, the Instrumentation Industries valve is designed with a 22-mm male connector for both its input and exhaust ports. It was easy to accidentally connect its exhaust port to the 22-mm female exhalation limb of the breathing circuit tubing, causing an occlusion and blocking ventilation. Care must be taken to ensure the valve is connected in the proper direction and at the proper port on the tubing. A connector must also be obtained for proper installation.

The Baxter tubing was found to be unsatisfactory due to the special modifications required to fit the Bear ventilator. Extensive cutting was required, with provided directions which were, at best, unclear. Also, using the disposable tubing, rather than the Bear tubing, may result in inaccurate inspiratory pressure, tidal volume, and flow. We strongly recommended that only the Bear patient breathing circuit be used with the ventilator.

CONSIDERATIONS

During the laboratory and inflight tests several technical and human factors problem areas were identified. To solve or prevent these potential problems in the operational environment, the following recommendations are made:

Procedural Recommendations

Check for Excess Fluid. During the vibration and inflight tests, excess fluid accumulated quickly in the breathing circuit, requiring disconnection and drainage approximately every 20 min. The fluid buildup may not be as much of a problem with a patient using the ventilator; however, we recommend frequent monitoring, and draining excess fluid as necessary.

Refilling the Humidifier. Before water can be added to the humidifier, the patient must be removed from the ventilator and manually ventilated. The humidifier must be disconnected from the ventilator before adding water to the humidifier. If an attempt is

made to add water while the Bear 33 is cycling, it will spew out through the filler port. However, users should not need to refill the humidifier during most aeromedical evacuation missions, as it took 6-8 h of sustained use before the level reached the "ADD WATER" mark.

Closely Monitor Alarms. The alarms must be closely monitored, as the audible alarms on the ventilator are difficult to hear in flight, even when standing close to the unit. The humidifier has visible alarms only. Bear Medical Systems, Inc. offers remote audible or visible alarms; however, because of EMI concerns, these alarms would need to be tested by this facility before being approved for use on aeromedical missions. Due to difficulty hearing or seeing the alarms, an attendant may be required to be positioned near the ventilator patient during takeoff and landing.

Monitor Control Panel. After all laboratory testing was completed, the ventilator was not operated for several days. The next time the ventilator was used, the unlock button stopped functioning. The unit was "locked" on and would not turn off. The Bear Medical Systems, Inc. technician who corrected the problem surmised that it may have been a chance occurrence; or one of durability, as the ventilator was operated often during 4 months of laboratory tests. Users should note and report if this problem reoccurs.

Patient Breathing Circuit. The Bear Patient Breathing Circuit Model 51000-08020 should be used with the ventilator. Use of any other breathing circuit could seriously affect performance and endanger the patient.

Suggested Modifications

Litter Sled. Replace the hexagonal J-bolt nuts, which secure the sled to the litter, with larger wing nuts. This modification will allow the sled to be adequately secured by finger tightening, without the need for tools. Also, the length of the J-bolts should be shortened; and the threads continued closer to the curve of the bolt. This extra threading will allow the J-bolt to be secured more tightly to the litter.

Carrying Case Handles. The carrying case was large and bulky and required 2 people to carry. The handles, which were in the middle of each side (1 handle per side), did not allow safe, stable carrying. The case tended to spontaneously rotate on the axis created at the center of the case where the handles were located, twisting the hands and wrists of the carriers. To correct the problem, the handles could be moved higher onto the lid or an additional handle could be added to each side.

Carrying Case Size. The carrying case is big and awkward, requiring 2 people to carry it. According to the manufacturer, the case size is a result of the 1.83-m (6-ft) drop contract requirement. We recommend that the drop requirement be waived, allowing the manufacturer to provide a smaller, more manageable carrying case.

Length of Breathing Circuit Tube. The ventilator will be secured to an equipment litter above or below the patient. A longer patient breathing tube may be needed if the

equipment litter is spaced more than 45.7 cm (18 in.) from the patient litter, and the ventilator not placed directly above or below the patient's head.

Oxygen Accumulator Chart. The oxygen accumulator chart determines the approximate flow for prescribed patient oxygen concentration. Ensure that the chart is included with the ventilator. If the Clinical Instruction Manual is carried with the ventilator, the chart is on page 6-9; if not, a chart should be attached to the ventilator.

Expanding Power Capabilities. Though not evaluated, normally the Bear ventilator can be operated from an external battery. The external battery would provide an added capability of using the ventilator on the C-12 and C-21. We evaluated form and fit of the ventilator on these aircraft and an external battery can be accommodated. However, if the users are interested in this option, we must test the Bear with the external battery before it can be recommended for use on aeromedical missions.

CONCLUSIONS

The Bear 33 Ventilator System passed all laboratory and inflight tests and is approved for use on the C-9, C-130, and C-141 with the following requirements:

Oxygen Analyzer. Always use an inline oxygen monitor when using the ventilator. During flight, as the altitude changes, oxygen flow will need to be increased or decreased to maintain a constant oxygen partial pressure.

Power Supply. The ventilator is not approved for use on any aircraft where an external power supply (110-120 VAC/60 Hz) is unavailable, either from the aircraft itself, or an approved power inverter or frequency converter. The ventilator can be operated on its internal battery only as the backup power supply; or during transition from aircraft to ambulance.

Humidifier Modifications. During vibration testing, several required modifications were identified for the humidifier. The gasket on the jar cover must be enlarged, and all internal screws must be locked in place. Only those humidifiers which have been modified should be used on aeromedical flights.

ACKNOWLEDGMENTS

We would like to thank all those who helped and advised us during the evaluation of the Bear Medical Systems, Inc. Bear 33 Volume Ventilator System. We would particularly like to thank Lt Col Mark Swedenburg, Lt Col Richard Knecht, Maj Garye Jensen, Capt Susan Nagel, 1Lt Rebecca Schultz, MSgt Rufino Navalta, MSgt Ernest Roy, MSgt Victor Elizondo, and TSgt R.J. Van Oss.

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2. AFR 160-3, Electrical Safety in Medical Treatment Facilities.
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4. MIL-STD-810D, Environmental Test Methods and Engineering Guidelines, Jul 83.
5. "Emergency Care Research Institute Health Devices," 1990.
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7. The Aeromedical Research Function Procedures Guide (Draft). USAF School of Aerospace Medicine, Brooks AFB, TX 78235, 1990.

APPENDIX A

SPECIFICATIONS AND OPERATING FEATURES OF THE BEAR 33 VOLUME VENTILATOR

Model: Bear 33

Part Number: 50000-00833/4

Manufacturer: Bear Medical Systems, Inc.
2085 Rustin Avenue
Riverside, CA 92507

1. The ventilator will operate in any position. Its operating ranges are:
 - a. Rate: 6 to 375 cycles/minute (adjusted by a single ventilation control knob)
 - b. I/E ratio: 1:1 through 1:5
 - c. Volume: 10 to 1,500 cm³
 - d. Delivery Pressure: 5 to 100 cmH₂O (determined by operational source gas pressure)
2. Physical dimensions:
 - a. Weight: 14.5 kg (32 lb)
 - b. Height: 19.2 cm (7.5 in.)
 - c. Width: 35.8 cm (14 in.)
 - d. Depth: 32.5 cm (12.8 in.)
3. Inlets:
 - a. Gas: Allows gas to be drawn into the cylinder. An optional 27-mm barb fitting allows concentrations of 21 to 100% to be drawn into the cylinder from an external reservoir.
 - b. Electrical:
 - (1) Nominal: 120 VAC/60 Hz; 12 VDC.
 - (2) Range: 96 to 132 VAC.

APPENDIX B

SPECIFICATIONS AND OPERATING FEATURES OF THE LS 420 HUMIDIFIER

Model: LS 420

Part Number: 50000-00420

Manufacturer: Bear Medical Systems, Inc.
2085 Rustin Avenue
Riverside, CA 92507

1. Physical dimensions:

- a. Weight: 3.04 kg (6.75 lb)
- b. Height: 30.5 cm (12 in.)
- c. Width: 17.8 cm (7 in.)
- d. Depth: 17.8 cm (7 in.)

2. Electrical Power Requirement: 110 VAC/60 Hz.